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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,482	02/19/2004	Peilin Guo	JARR-139	5653

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MCCARTER & ENGLISH LLP
CITYPLACE I
185 ASYLUM STREET
HARTFORD, CT 06103

EXAMINER

FERNANDEZ, SUSAN EMILY

ART UNIT PAPER NUMBER

1651

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/782,482

Applicant(s)

GUO, PEILIN

Examiner

Susan E. Fernandez

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☒ Claim(s) 1-3 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/18/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Handwritten initials: HJ

DETAILED ACTION

Claims 1-16 are pending and are presented for examination.

Election/Restrictions

Applicant's election with traverse of *Lactobacilus rhamnosus* of claim 3 in the reply filed on June 10, 2005, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-16 are examined on the merits to the extent they read on the elected subject matter.

Claim Objections

Claims 1-3 are objected to because of the following informalities: Claim 1 should end with a period. Also, *Lactobacilus* recited in claims 2 and 3 should be spelled as *Lactobacillus*. Additional misspellings are present in claim 3 (helveticu, thermphilus). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 12 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is rendered indefinite by the term, "MOS". "MOS" should be defined as "mannanoligosaccharide" at the first instance it appears in the claims. Thus, claims 12 and 15 are rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, and 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by De Jong et al. (WO 00/33854).

De Jong et al. discloses a preparation for the "prevention and/or treatment of disorders of the digestive tract" (claim 1). In particular, see claims 1, 3, 6, 7, and 9. The preparation comprises of one or more probiotic microorganisms and one or more non-digestible oligosaccharide (claim 1). Moreover, the preparation may comprise of the combination of one bacterial strain and one yeast strain (claim 6), where the bacterial species may be *Lactobacillus acidophilus* or *Lactobacillus rhamnosus* (page 4, lines 4-6), and the yeast species may be *Saccharomyces cerevisiae* (page 4, lines 7-10). Additionally, De Jong et al. states that "if dead *Saccharomyces cerevisiae* is also used, this is administered in a quantity of 0.5 to 5 g per day"

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(page 4, lines 26-27). According to the application under examination, mannanoligosaccharides (MOS) are present in “the cell walls of yeast, such as *Saccharomyces cerevisiae*” (page 7, lines 6-7). Similarly, White et al. (Journal of Animal Science, 2002, 80: 2619-2628) notes that *S. cerevisiae* (brewer’s yeast) is a source of MOS, and that the MOS content of the yeast is 5.2% (page 2620, first column, fourth paragraph). Thus, a composition comprising *S. cerevisiae* also comprises MOS. In addition to suitable probiotics, De Jong et al. specifies suitable oligosaccharides, which includes fructo-oligosaccharides (FOS) (page 2, lines 28-29). Claim 9 of De Jong et al., recites a ratio of 1 to 5 g oligosaccharides per 10^8 to 10^{11} cells of the probiotic, and indicates that “the total concentration of probiotics is 10^6 to 10^{12} ...live cells per gram of total product” (page 4, lines 20-21). Depending on the masses of *S. cerevisiae*, fructo-oligosaccharide, and *L. acidophilus* or *L. rhamnosus* used in a preparation meeting the requirements of De Jong et al., limitations recited in claims 4-8 of the application under examination are met.

Example II, a synbiotic bar, is one suitable preparation (page 8, line 5-8). The 23 gram bar comprises of 1 gram of *L. rhamnosus*, 0.5 gram of brewer’s yeast, and 5 gram of an oligosaccharide. Thus, the bar of Example II comprises as few as $2.3 * 10^7$ live cells (23 g total product * 10^6 live cell/g total product). A colony forming unit (CFU) can comprise of only a single cell, thus the bar of Example II may comprise of $2.3 * 10^7$ CFU of *L. rhamnosus*. Since De Jong et al. specifies that 0.5 to 5 g of dead *S. cerevisiae* may be administered per day (page 4, lines 26-27), a daily intake of a one to ten synbiotic bars is appropriate. If 5 g of *S. cerevisiae* is administered in a day, 260 mg MOS is administered daily (5 g yeast * 0.052). Moreover, a daily intake of ten synbiotic bars results in a daily intake of 260 mg MOS, $2.3 * 10^8$ CFU of *L.*

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rhamnosus, and 50 grams of oligosaccharides (transgalacto-oligosaccharides). Thus, limitations of claims 12 and 13 are met.

Additionally, ten synbiotic bars combined together would be considered a "composition for improving gastrointestinal tract health", where said composition comprises 260 mg MOS, and 2.3×10^8 CFU of *L. rhamnosus*. Thus, the limitations of claims 11-13 of the application under examination are met. A holding of anticipation is clearly required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8, 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Jong et al.

As discussed above, De Jong et al. anticipates claims 1-8, and 11-14.

De Jong et al. does not expressly disclose administering fructooligosaccharide to achieve a daily intake ranging from 100 mg to 25 g.

Since a daily intake of 2.3×10^8 CFU of *L. rhamnosus* is appropriate (based on information about the synbiotic bar), and given claim 9 of De Jong et al., a minimum of 2.3 g of oligosaccharide, such as fructooligosaccharide, is suitable for daily intake.

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At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have administered 100 mg to 25 g of fructooligosaccharides per day by the intake of a preparation disclosed in De Jong et al.

One of ordinary skill in the art would have been motivated to do this since De Jong et al. indicates in claim 9 a wide range of suitable proportions of oligosaccharide to probiotic. Additionally, the selection of a particular daily dose (whether of fructooligosaccharides, *S. cerevisiae*, and *L. rhamnosus* or *L. acidophilus*) would have been a routine matter of optimizing a result-effective parameter at the time of applicant's invention. A holding of obviousness is clearly required.

Claims 1-14 rejected under 35 U.S.C. 103(a) as being unpatentable over De Jong et al. in view of Sorkin, Jr. (US 5,952,393).

As discussed above, De Jong et al. anticipates claims 1-8 and 11-14.

De Jong et al. does not expressly disclose compositions comprising at least one formulation aid recited in claims 9 and 10.

Sorkin, Jr. discloses a composition comprising "pharmaceutically acceptable formulation aids, such as diluents, stabilizers, binders, buffers, lubricants, coating agents, preservatives, emulsifiers and suspension agents" (column 2, lines 11-15).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have included at least one of the formulation aid in the preparation taught by De Jong et al., such as those listed in Sorkin, Jr.

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One of ordinary skill in the art would have been motivated to do this since both compositions taught by De Jong et al. and Sorkin, Jr. are for treatment in humans. Furthermore, the formulation aids are safe for administration in humans since the formulation aids are "pharmaceutically acceptable". These formulation aids would not have interfered with the activities of the De Jong preparation, as they had been found suitable for the Sorkin, Jr. preparation. Thus, a holding of obviousness is required.

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan E. Fernandez
Assistant Examiner
Art Unit 1651

sef



FRANCISCO PRATS
PRIMARY EXAMINER